Remarks

Claims 4, 8-14, 16, 18, and 20-24, 26-29, and 31-38 are pending in this application. No claim amendments are made in this response. Applicant believes the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Finality of Office Action

As an initial matter, the Examiner made the Office Action final based on a new ground of rejection not stated in the earlier Office Action. Applicants respectfully traverse this decision. In the Final Office Action, the Examiner rejects the present claims by citing Bonutti (US 5,593,425). Applicant respectfully points out that the Bonutti reference was not cited by the Examiner in any previous Office Action.

According to MPEP § 706.07(a): "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection not necessitated by amendment of the application by applicant, whether or not the prior art is already of record." The Applicant has not amended the claims since the last rejection, and did not switch from one subject matter to another, or resort to any subterfuge to keep the application pending. (See MPEP See MPEP § 706.07). Thus it is respectfully submitted that the final status of the Office Action is premature and should be withdrawn.

If the Examiner does not withdraw the final status of the Office Action, Applicants submit that this response does not raise new issues in the application. It is submitted that the present response places the application in condition for allowance or, at least, presents the application in better form for appeal. Entry of the present response is therefore respectfully requested.

Rejection under 35 U.S.C. §102

Claims 4, 8-14, 16, 18, 20-24, 26-29, and 31-38 were rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 5,593,425 to Bonutti et al. (hereinafter "'425 Patent").

In response, Applicant respectfully submits that this rejection should be withdrawn.

The '425 Patent relates to an assembly for use in surgical applications that may include two components, at least one of which comprises a heat bondable material. (Col. 1, lns. 40-43). The first and second components are bonded to each other by the application of heat to the heat bondable material, to make the heat bondable material soften, become tacky, and bond to the other component. (Id).

The rejection states that the '425 Patent discloses the claimed invention in Figures 2 and 10-11C.

With reference to Fig. 2 of the '425 Patent, a fastener extends completely through a tissue mass such as a bone 160, for example to secure a plate in position against the bone. (Col. 4, lns. 47-48). An elongate fastener 162, which may be metal or may be made of or include a bondable material, is inserted through an opening in the bone 160. (Id). A distal fastener 164 is secured to the distal end of the screw 162 by a plug of bonded material 166. (Id). The plate 168 is then placed over the bone screw, and a proximal fastener 170 made of or including a bondable material is bonded to either or both of the screw 162 and the plate 168. (Id). The elongate fastener 162 may optionally also be threaded in the portion engaging the bone 160. (Id). The elongate fastener 162 may optionally also be threaded in the portion engaging the fastener 164 and/or the fastener 170. ***Thus, Fig. 2 discloses only one bone plate. Furthermore, the embodiment of Fig. 2 does not disclose the use of a suture.***

With reference to Fig. 10, the '425 patent discloses the use of bonded fastenings in conjunction with a curved opening in tissue parts to be joined. (Col. 8, lns. 55-57). Two portions 172 and 174 of a fractured bone with their ends abutting at a joint 176 are secured together with a suture which extends axially through the fractured ends of the bone, ***while accessing the joint only from one side of the bone***. (Id). A curved opening 178 is drilled through the first bone part 172 and the second bone part 174 and a suture 180 is then passed through the opening 178. (Id). A first fastener 182 made of or including a bondable plastic material is then bonded onto the protruding end of the suture 180. (Id). The suture is then pulled tight, and a second fastener 184 also made of or including a bondable material is pulled down

tight against the proximal face of the second bone part 174 and bonded by heating in location to the suture 180. (Id). ***Thus, the embodiment disclosed in Fig. 10 of the '425 Patent includes bondable plastic fasteners only, with both connectors on one side of the bone only, rather than opposite each other.***

With reference to Figs. 11A-11C, the '425 patent discloses the use of a bonded fastening in conjunction with a rivet type fastening. (Col. 9, lns. 9-12). To secure together two adjoining masses 186 and 188, a sleeve 190 is inserted through an opening in the tissues until the distal end 192 of the sleeve projects behind the tissue 186. (Id). A mandrel 194 in the sleeve 190 has a headed portion 196 at its distal end 192. (Id). The mandrel 194 is then pulled outwardly, while the sleeve 190 is held in place, spreading the distal end 192 of the sleeve to lock the sleeve in place behind tissue 186. (Id). The protruding end of the mandrel 194 is then cut off flush with and bonded by heating as at 198 to the head end 200 of the sleeve. ***Thus, the embodiments disclosed in Figs. 11A-11C do not include two separate bone plates opposite each other, and do not disclose the use of a suture.***

Claim 4 recites a bone suture assembly for treating a fracture of a bone comprising: a first rigid bone plate positionable proximate to the bone; a second rigid bone plate positionable proximate to the bone generally opposite the first bone plate; a suture connected with the first and second rigid bone plates to thereby stabilize the fracture, the suture positionable through a passage in the bone; and at least one fastener positionable through the first rigid bone plate into the bone to hold the first rigid bone plate to the bone.

Thus, as described above, the '425 Patent fails to disclose the use of two bone plates positioned opposite each other and connected by a suture. Specifically, the embodiments of Figs. 2 and 11A-11C of the '425 Patent do not involve the any use of a suture, and do not disclose two bone plates. The embodiment of Fig. 10 discloses two bondable fasteners instead of two bone plates. Furthermore, the two fasteners of Fig. 10 are both on the same side of the bone instead of positioned opposite of each other.

In addition, the '425 patent does not disclose, in combination with a suture holding bone together as claimed, a fastener positionable through a bone plate into the bone to hold the plate to the bone. The '425 Patent contemplates only a single, new type of fastener. As stated in the '425 Patent: "As noted, ordinarily a bone plate is held to bone via a threaded fastener such as the bone screw 14 or 20 in FIG. 1. However, the bone is alive and is constantly remodeling the threads on the bone screw. As this happens, the fastener loses its purchase or holding power in the bone, and the screw can pull loose. Accordingly, it would be desirable to obtain more purchase by a different kind of fastener." (Col. 4, lns. 38-44).

Claim 8 recites, a bone suture assembly for treating a fracture of a bone comprising: a first bone plate positionable proximate to the bone; a suture positionable through the first bone plate and across the fracture of the bone to thereby stabilize the fracture; and a tubular member positionable in the bone through the fracture, generally orthogonal to the first bone plate, wherein the tubular member remains in the bone such that the suture is disposed within the tubular member.

Thus, as described above, the '425 Patent fails to disclose a tubular member positionable in the bone and generally orthogonal to the first bone plate, wherein the tubular member remains in the bone such that the suture is disposed within the tubular member. While Fig. 2 of the '425 Patent shows a fastener orthogonal to a bone plate, the fastener is not taught to be hollow or have any opening through which a suture could be disposed. More particularly, there is no disclosure or suggestion of using a suture in combination with elongated fastener 162. Moreover, fastener 162 would be too long, even if hollow, to serve as a passage for a suture which passes through a bone plate and across the fracture of a bone to thereby stabilize the fracture.

Claim 13 recites, a bone suture assembly for treating a fracture of a bone comprising: a first suture anchor positionable proximate to the bone; a rigid bone plate positionable between the first suture anchor and the bone, the rigid bone plate and first suture anchor positionable generally on the same side of the bone; a suture extending through the rigid bone plate and

connected with the first suture anchor, the suture positionable across the bone to thereby stabilize the fracture; and at least one fastener positionable through the rigid bone plate into the bone to hold the rigid bone plate to the bone.

Thus, as described above, the '425 patent fails to disclose a suture extending through a rigid bone plate. Although Fig. 10 of the '425 patent shows a suture passing through a fracture, the suture does not extend through a rigid bone plate, nor is there disclosed the use of a fastener that extends into the bone to hold a rigid bone plate to the bone, in combination with the claimed suture. The embodiment of Fig. 10 discloses two bondable fasteners that are positioned completely outside of the bone, fastened only to the suture. .

Claim 23 recites, a method for treating a fracture of a bone comprising: forming at least one passage through the bone, where the passage traverses the fracture; positioning at least one suture anchor proximate to the bone; positioning at least one bone plate between at least one suture anchor and the bone; fastening the at least one bone plate to the bone with at least one screw; moving at least one suture through the passage in the bone and through at least one bone plate; attaching at least one suture to at least one suture anchor; and tensioning at least one suture to stabilize the fracture of the bone.

As described above, the '425 patent fails to disclose or teach a method according to Claim 23 because critical elements are lacking from the embodiments disclosed in Fig. 2, 10, and 11A-C. Figs. 2 and 11A-C lack any use of a suture, Fig. 10 does not involve any rigid bone plates or screws, and no bone plates are additionally fastened to the bone.

Accordingly, Applicant respectfully submits that independent claims 4, 8, 13, and 23 are patentable over the '425 Patent. As claims 11-12 and 35-38 depend from claim 4; claims 9-10 depend from claim 8; claims 14, 16, 18, 20-22, and 34 depend from claim 13; and claims 24, 26-29, and 31-33 depend from claim 23, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the '425 Patent for at least the same reasons.

In light of the foregoing, Applicant request reconsideration and withdrawal of the §102 rejections.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due for this submission. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-009-3).

Respectfully submitted,

/ Paul D. Bianco /

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